

FEB 7 2013

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MEDICAL

This 510(k) summary information is being submitted in accordance with the requirements of  
SMDA 1990 and 21 CFR 807.92.

**GENERAL INFORMATION**

**APPLICANT:** Dallen Medical, Inc.  
1046 Calle Recodo, Suite G  
San Clemente, CA 92673  
(949) 218-0030  
(949) 218-0040 Fax

**CONTACT PERSON:** Al Memmolo  
Chief Operating Officer

**DATE PREPARED:** September 17, 2012

**DEVICE DESCRIPTION:**

**TRADE NAME:** Compressyn™ Staple

**GENERIC/COMMON NAME** Fixation Staple

**CLASSIFICATION NAME:** Single/multiple component metallic bone fixation appliances  
and accessories, CFR 888.3030 (code JDR)

**DEVICE CLASSIFICATION:** Class II

**PREDICATE DEVICES:** Wright Medical Compression Staple (K043059)  
Biomedical Enterprises OSStaple Staple System (K993714,  
K001354)  
3M Bone Stapling Fixation System (K840566)

**Product Description:**

The Compressyn™ Staple consists of a stainless steel staple held on a carriage delivered by a pneumatic delivery device. The staple is offered in several sizes with barbs to prevent back out. It is a compression staple fixation device that is placed into two tissue segments using pre-drilled holes to provide stabilized fixation.

**Indications for Use:**

The Compressyn™ Staple is intended for: 1) hand and foot bone fragment and osteotomy fixation and joint arthrodesis, 2) fixation of proximal tibial metaphysis osteotomy, 3) adjunctive fixation of small bone fragments. These fragments may be located in long bones such as the femur, fibula and tibia in the lower extremity; the humerus, ulna or radius in the upper extremities; the clavicle and ribs; and in the flat bones such as the pelvis, scapula and sternum.

**Technical Characteristics:**

The Compressyn™ Staple has similar physical and technical characteristics to the predicate devices.

**Performance Data:**

Verification testing has been performed with the Compressyn™ Staple to assure substantial equivalence to the predicate devices. Comparative testing in comparison to predicate devices included the following tests:

The Compressyn™ Staple conforms to ASTM F564-10 Standard Specification and Test Methods for Metallic Bone Staples. Comparative compression force testing was also performed and the Compressyn Staple was shown to be substantially equivalent to the predicates.

The testing demonstrated that the Compressyn™ Staple is substantially equivalent to the predicate devices.

**Basis for Determination of Substantial Equivalence:**

Upon reviewing the safety and efficacy information provided in this submission and comparing intended use, principle of operation, performance data, and overall technological characteristics, the Compressyn™ Staple is determined by Dallen Medical to be substantially equivalent to existing legally marketed devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center - WO66-G609  
Silver Spring, MD 20993-0002

Dallen Medical, Incorporated  
% Mr. Al Memmolo  
Chief Operating Officer  
1046 Calle Recodo, Suite G  
San Clemente, California 92673

Letter dated: February 7, 2013

Re: K122871

Trade/Device Name: Compressyn™ Staple

Regulation Number: 21 CFR 888.3030

Regulation Name: Single/multiple component metallic bone fixation appliances and accessories

Regulatory Class: Class II

Product Code: JDR

Dated: December 21, 2012

Received: December 26, 2012

Dear Mr. Memmolo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA).

You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

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forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

**Mark N. Melkerson**

Mark N. Melkerson  
Director  
Division of Orthopedic Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

### Indications for Use Statement

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510(k) Number (if known): K122871

Device Name: **Compressyn™ Staple**

Indications for Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Anton E. Dmitriev, PhD

Division of Orthopedic Devices

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*Prescription Use* \_\_\_\_\_  
(Per 21 CFR 801.109)

OR

*Over-The-Counter Use* \_\_\_\_\_